

## 2005-06 Influenza Vaccine Supply and Vaccine Recommendations CDC's Key Messages (October 18, 2005)

### Overall

- ***Patience, persistence, and cooperation are needed as the nation's influenza vaccine is becoming available and vaccination efforts begin.*** As we start our immunization efforts, vaccine availability is less than ideal, but this year, CDC is recommending that the first available doses be provided to the people in priority groups (e.g., people 65 years old and older, people with respiratory, heart, and other chronic conditions, pregnant women, 6-to-23-month old children, health care personnel, residents of long-term care facilities). Some of these people may initially find that getting vaccinated will take a little patience and persistence— people may have to call their health care provider or make a vaccination appointment, but we are hopeful over the coming weeks, vaccine will be more widely available.
- ***We are pleased to see so much early interest in receiving and providing influenza vaccine, but everyone should keep in mind that ample time remains to provide and receive influenza vaccine.*** The 2005-06 influenza vaccination season has just begun, and the influenza disease season has not started. Influenza disease typically does not peak in the United States until January or later.
- ***We want people, particularly those in the priority groups, to receive an influenza vaccination. Health care providers who have received some influenza vaccine should look for opportunities to use that vaccine to reach people in the priority vaccination groups*** – this could include efforts in physician offices, senior centers, assisted living centers, or other sites where priority people can be reached and clear messages can be offered about who can receive vaccine and when.
- ***As the past influenza seasons have illustrated, the mostly private sector nature of the U.S. influenza vaccine system can cause frustration and challenges for some providers of influenza vaccine.*** The Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) are committed, however, to addressing concerns and challenges, and do so by promoting collaboration and cooperation among the many organizations involved in influenza vaccination, and greater commitment to the development and production of influenza vaccination. CDC and its partners, including the National Influenza Vaccine Summit, will review the experiences of vaccine supply and distribution of 2005-06, and make recommendations for improvements for 2006-07.

### Influenza Vaccine Distribution/Use

Projected vaccine production includes the following amounts by each company:

sanofi pasteur	60 million doses
GlaxoSmithKline	7.5 million doses
MedImmune	3 million doses
Chiron	The company now expects that the total number of Fluvirin® vaccine doses it will produce for the 2005-2006 influenza season will be below its previously stated range [18 million to 26 million doses] due to production delays related to remediation as well as lower production output associated with adaptation to new processes and procedures implemented in remediation. For more details, go to <a href="http://www.chiron.com">www.chiron.com</a>

Through September, approximately 28 million doses of influenza vaccine have been distributed. Through October, it is projected that approximately 57 million doses will have been distributed nationally, and a total of 80+ million doses are projected to be distributed by the end of November. Up to 90 million doses could potentially be distributed this season if demand warrants late season distribution, including utilization of the influenza vaccine stockpile.

As of October 12, 2005, all four manufacturers had vaccine lots released for distribution by the Food and Drug Administration. Typically, once a lot is released by the FDA, the manufacturer completes its internal lot release protocol and begins shipping vaccine from that lot to distributors or end users in one to two weeks. For the latest information on influenza vaccine lot releases, please see <http://www.fda.gov/cber/flu/flu2005.htm>.

- ***Influenza vaccine cannot be produced so that the entire supply is available at once***; rather, while vaccine begins to become available in late summer, production and distribution often continue into December and even January.
- ***All four of the U.S.-licensed influenza vaccine manufacturers are producing and distributing their influenza vaccine on different timetables.***
  - Sanofi pasteur is trying to provide all those who placed orders with their company some vaccine - - that is, providing their customers with partial orders (e.g., 20% of the order) and filling the rest of each order in the coming weeks. CDC has endorsed sanofi pasteur's approach to the distribution of vaccine in partial shipments and has encouraged other vaccine distributors to adopt it. This process allows almost all their customers to begin their vaccination efforts as early as possible. Following is a statement from sanofi pasteur dated October 13, 2005.

“Sanofi pasteur, the vaccines business of the sanofi-aventis Group, is ahead of its influenza vaccine shipping schedule to provide 60 million doses for the 2005-2006 immunization season. The company began shipping influenza vaccine to customers during the first week of August. Approximately 45 million doses will be shipped by the end of October. To date, approximately 95 percent of sanofi pasteur customers have received at least a partial delivery of their orders, which allows them to begin immunizing their high-risk patients.

The company will continue to ship vaccine as quickly as possible on a continuous basis into November, with shipping expected to be completed by the middle of November, six weeks ahead of its initial forecast. This split-delivery distribution process was initiated by sanofi pasteur several years ago in support of the U.S. Centers for Disease Control and Prevention's (CDC) recommendation for immunization prioritization.”

- If an influenza vaccine provider did not place an order with sanofi pasteur, and ordered from a distributor, they may have received some vaccine (either the GlaxoSmithKline or sanofi pasteur brand) or should be receiving vaccine soon (i.e., in the coming weeks).
- Those placing orders with a distributor for Chiron's vaccine will experience the greatest delays since Chiron's product is just becoming available for distribution.
- Those ordering the nasal-spray vaccine, FluMist<sup>®</sup>, appear to be receiving their orders in a timely way.

- ***Many different types of health care settings provide influenza vaccine annually.*** The following data are derived from CDC's Behavioral Risk Factor Surveillance System, and they compare venues where influenza vaccine was administered in 2001, the most recent non-shortage year for which complete data are available, and 2004 when an influenza vaccine shortage occurred.

<b>Vaccination Venue</b>	<b>2001</b>	<b>2004</b>
Doctor's Office or HMO	43.81%	40.38%
Health Department	5.11%	10.34%
Clinic or Health Center	11.26%	12.10%
Community Center	3.05%	4.12%
Store	6.07%	6.19%
Hospital or Emergency Room	5.23%	7.61%
Workplace	19.71%	11.71%
Other	5.77%	7.54%
Total	100.00%	100.00%

The 2004 influenza vaccine shortage resulted in a substantial reduction in workplace vaccination and a 3.4 percentage point decline in doses administered by private physicians. Public health departments doubled their rate to 10 percent and hospital/emergency room vaccination increased slightly. Given current circumstances, including a delay in distribution of part of this year's vaccine supply, we would expect that in 2005, vaccine administration by venue would resemble what occurred in 2001.

- ***CDC values the contributions of all healthcare organizations and providers to influenza vaccination, and prefers that all have similar access to influenza vaccine.*** Health care providers and health departments which have not received enough influenza vaccine for their priority patients are concerned that their patients may not be vaccinated, particularly if they are caring for underserved persons with limited options for health care (who may not be able to receive vaccine at a community vaccination clinic). ***We are hopeful that they will have vaccine soon.***

### **Influenza Vaccination Recommendations**

- ***CDC and HHS attempt to influence influenza vaccine distribution and use through recommendations, guidelines, and extensive collaborations.*** The Centers for Disease Control and Prevention (CDC) does not usually buy or distribute influenza vaccine - - the vast majority of doses are purchased and provided by state and local health departments and private healthcare providers. However, CDC encourages wide adoption of its influenza vaccination recommendations, and works with state and local health departments, professional medical organizations, vaccine manufacturers, and other influenza vaccine providers to achieve the highest rates of cooperation possible.
- While encouraging that available influenza vaccine be directed to people in priority groups, CDC recommends using strategies that minimize the amount of time people spend waiting in lines, including scheduling appointments.

***We do not yet know if CDC's recommendation to direct the currently available doses of influenza vaccine to people in priority groups is successful.*** CDC, state and local health departments and other stakeholder organizations have received some reports that certain influenza vaccine providers are not following the recommendation, but upon further investigation, many of these reports prove to be unfounded. Compliance with CDC's recommendation is voluntary except in states that have chosen to invoke a rule, regulation, statute or legal order to mandate it. Nevertheless, most health care providers, including community or "mass" vaccinators, are following and promoting the recommendation. ***Last year, this strategy effectively directed most of the available vaccine to people in the priority groups.***